Remarks

Claims 1-18 were originally presented for examination. Claims 1-12, and 17-18 were withdrawn from consideration pursuant to a restriction and election of species requirement. Claims 13-16 remain in the application and are presented for examination.

Claims 13 and 16 have been amended as shown above. No claims have been added or cancelled.

The Examiner has indicated that the restriction/election requirement was withdrawn with respect to claim 14. Applicants acknowledge this with appreciation.

The Examiner has continued to object to the Abstract. In response, Applicants has amended the Abstract as shown above. Applicants believe that the amended Abstract overcomes the Examiner's objection.

The Examiner has indicated that, with regard to claims 13 and 16, "...the Applicants have invoked 35 U.S.C. 112 6th paragraph by using 'means for' language reciting function and, not reciting sufficient structure of the means referred to in the specification." Specifically, the Examiner has objected to the language "storage means for storing a drug" and "metering means for...amount of the drug" as invoking 35 USC 112, sixth paragraph without reciting sufficient structure. Applicants have amended claim 13 to delete these two "means" and replace them with a "storage area" and a "meter" respectively. Applicants submit that these amendments overcome the Examiner's objections.

The Examiner has rejected claim 16 under 35 USC 112, first paragraph as containing subject matter that was not described in the specification. Applicants have amended claims 16 to remove the language specifying that there is an effective amount of the substance that resists occlusion of the drug delivery path. In its place Applicants have recited that the substance is in the drug delivery ports. Applicants submit that this overcomes the Examiner's rejection of claim 16 under 35 USC 112, first paragraph.

Rejections

Claims 13, 15 and 16 have been rejected under 35 U.S.C. 102(b) over U. S. Patent 5,041,107 (hereinafter Heil). Claim 14 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Heil in view of U.S. Patent 5,520,672 (hereinafter Urry). Applicants traverse these rejections for the reasons set forth below.

Argument

The Rejection Under 35 U.S.C. 102(b)

The Examiner argues that Heil discloses an implantable drug delivery system having a storage means for storing a drug, a metering means for delivering a predetermined, effective amount of the drug through a drive electrode, a power source and oppositely charged return electrode, a delivery means for delivering an effective amount of the drug. He further argues that delivery means comprises a catheter that has a longitudinal axis and a plurality of drug delivery slits that are moveable between open and closed positions. He further argues that Heil discloses a drug delivery path preservation means for resisting fibrous occlusion proximate and in the drug delivery ports comprising a substance for resisting fibrous occlusions of the drug delivery ports. The Examiner notes that the portion of the catheter body where the film or membrane is attached is proximate and structures over the drug delivery port is a substance that resists formation of fibrous occlusions. Specifically, he cites column 4, lines 36-46 in support of this argument. Applicants disagree with the Examiner's analysis.

Heil discloses an electrically controllable, non-occluding, body implantable drug delivery system. This system employs a **self-sealing slit** as a drug delivery site (see, col. 2, lines 22-23; col. 3, lines 52-56; col. 4, lines 6-12; and col. 4, lines 38-43). Self –sealing is achieved by either (a) providing a cut at an angle to the wall of the device so as to increase the amount of wall material intersected by the slit and prevent the ingress of blood or other tissue, or (b) providing a port covered by a membrane or film that acts as a physical barrier to the ingress of blood or other tissue. Thus, Heil only discloses preventing occlusion of the drug delivery slits by a physical barrier. Heil does not teach the delivery of a substance to the drug delivery ports that resists fibrous occlusion. Consequently, Heil does not teach at least one required element of the claimed invention and therefore fails to support the rejection of claims 13-16 under 35 U.S.C. 102(b).

The Rejection Under 35 U.S.C.103(a)

As shown above, Heil only teaches the use of a physical barrier to prevent occlusion of the drug delivery slits. Therefore, it does not disclose the present invention substantially as claimed. Heil also fails to suggest the replacement of his physical barrier with a substance that resists occlusion. Consequently, Heil fails to supply any logic why one should replace the physical barrier with such a substance.

Urry fails to supply any reason to replace the physical barrier with such a substance. This reference is directed to a superabsorbent polymer and uses thereof. These polymers are taught to have absorbent properties that can switch between a swollen state and a contracted state depending upon the environment in which they are used.

Urry does not disclose the use of these materials as a drug delivery catheter that has a plurality of drug delivery ports. Thus it provides no motivation to use the polymers disclosed there in such a use, let alone as a substance for resisting the fibrous occlusion of the drug delivery ports of the catheter. As a result, there is no motivation to make such a substitution and the combination of Urry with Heil does not support the rejection of claim 14 under 35 U.S.C. 103(a).

Conclusion

Based on the preceding comments, Applicants submit that they have shown that claims 13-16 are patentable over the Rise and Heil references. They request reconsideration of the rejections and allowance of all claims.

The Examiner is invited to contact the undersigned, at the Examiner's convenience, should the Examiner have any questions regarding this communication or the present patent application.

Respectfully Submitted,

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